

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Clifton D. Crutchfield      DOCKET NO.: 121934.00002  
SERIAL NO.: 10/599,953      EXAMINER: Valerie Lynn Skorupa  
FILED: 10/13/2006      ART UNIT: 3771  
CONFIRMATION NO.: 7175

TITLE: Respirator Fit-Testing Apparatus and Method

MAIL STOP - Amendment  
Commissioner for Patents  
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CERTIFICATE OF EFS-WEB TRANSMISSION

I hereby certify that on this 18<sup>th</sup> day of November, 2010, this correspondence is being transmitted to the Commissioner for Patents, United States Patent and Trademark Office, via EFS Web.

  
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Alice Vanicek

TO THE COMMISSIONER FOR PATENTS

DECLARATION BY  
Clifton D. Crutchfield, Ph.D.

I, Dr. Clifton D. Crutchfield, hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that I have full knowledge and understanding of the fact that willful false statements and the like made herein are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that any such statements may jeopardize the validity of the above-referenced application or of any patent granted on it.

1. I hold a B.S. from the United States Air Force Academy in Engineering Management (1969), a MSPH from the University of North Carolina in Industrial Hygiene (1975), and a Ph.D. from the University of North Carolina in Environmental Sciences and Engineering (1978).

2. After graduating from the United States Air Force Academy, I attained the rank of Colonel and title of Chief Bioenvironmental Engineer in the United States Air Force.

3. Prior to my retirement, I was an associate professor, a researcher, and an administrator at the University of Arizona for over 20 years in the area of industrial hygiene.

4. Based on the foregoing, I have become an internationally recognized expert in the area of respirator fit testing and developed the controlled negative pressure fit test method that is used throughout the industrial hygiene field today for fit testing respirators.

5. I have read and understood the subject U.S. Patent Application Serial No. 10/599,953 covering respirator fit-testing apparatus and methods.

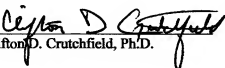
6. I also have read the Office Action from the Patent Office dated September 02, 2010.

7. In the arguments made especially on pages 3, 7 and 8 of the Office Action, the Examiner contends that if a mask wearer is instructed to hold his breath while the breathing port/air valve is open, then the mask interior will necessarily reach ambient pressure prior to the breathing port being closed and the fit testing commencing. This is not the case. Experience has shown that a mask wearer often continues to breath (consciously or unconsciously) after being instructed to hold his breath. This frequently results in the intra-mask pressure being either well above or well below ambient pressure when the breathing valve is closed, and, thus, too low or too high for accurate fit testing to be determined within the relatively short time frame required (a mask wearer must be allowed to breath within about 8 seconds after holding his breath to avoid wearer discomfort and testing complications caused by movement, etc.).

8. In contrast to the disclosure of the subject application, which is specifically aimed at overcoming the problem of "imprecise breath holding" as described above, I do not see any disclosure in the cited reference (U.S. 4,765,325) that teaches or suggests a respirator fit-testing protocol in which ambient pressure inside the mask is achieved prior to closing the breathing valve and initiating the fit testing as claimed in the subject application.

9. Accordingly, a person of ordinary skill would not find the invention of claim 1 to be obvious in view of U.S. 4,765,325 because at least step (c) ("activating a switch that closes a breathing port of said respirator, thereby initiating a controlled negative pressure testing protocol, when intra-respirator pressure substantially equals ambient pressure") is not disclosed or suggested.

Respectfully submitted,

By:  Dated: 11/18/2010  
Clifton D. Crutchfield, Ph.D.